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COVID-19 Information

Revisions from 4/10/2020 in Green Revisions from 4/14/2020 in Purple

BOARD OPERATIONS

Beginning April 6, 2020, the Board office will re-open. *To enforce social distancing requirements, the office will continue to be closed to walk-in customers and drop-offs.* Additionally, the Board will have minimal capacity to answer phones and asks that consumers, licensees, and registrants use email as the primary method of communication with our staff. Contact information can be found here. The Board will continue to receive and respond to mail, email, and fax correspondence. Changes to service offerings, applications, or renewals are not planned. However, the Board anticipates that response times will be longer and appreciates patience.

The Kansas Prescription Drug Monitoring Program, K-TRACS, will maintain core functions to ensure the system remains fully operational during this time. If you have questions, concerns, or need assistance please e-mail pmpadmin@ks.gov. Due to a limited number of staff, response times may be longer than normal.

The Board will continue to assess the COVID-19 situation in conjunction with the State of Kansas.

GUIDANCE FROM STATE AND FEDERAL PARTNERS

The Kansas Department of Health and Environment has a COVID-19 Resource Center on their website which allows consumers to subscribe to updates and provides links to frequently asked questions and CDC coronavirus information.

KDHE http://www.kdheks.gov/coronavirus

1-866-534-3463 (1-866-KDHEINF)

Monday-Friday 8am-7pm, Saturday 10am-2pm, and Sunday from 1pm-5pm

CDC https://www.cdc.gov/coronavirus/2019-ncov/hcp/index.html

DEA https://www.deadiversion.usdoj.gov/coronavirus.html

FDA https://www.fda.gov/emergency-preparedness-and-response/counterterrorism-and-

emerging-threats/coronavirus-disease-2019-covid-19

Critical Point https://peernetwork.criticalpoint.info/ Register for free peer network level.

NABP https://nabp.pharmacy/coronavirus-updates/

KPhA https://www.pharmacist.com/coronavirus

APhA https://kansaspharmacistsassociation.wildapricot.org/COVID-19

Joint Commission Link to COVID-19 Guidance

BEST PRACTICE RECOMMENDATIONS

To minimize contact and spread of COVID-19, the Board recommends pharmacies encourage customers to utilize drive-throughs where they are available. The Board also recommends requesting customers space themselves out when waiting in line and that the pharmacy consider the use of some sort of counter extension to establish a larger gap between the customer and the cashier, where possible.

CLEANING AND DETECTION

Pharmacists should use their professional judgment to ensure policies and procedures are in place to protect Kansas patients. The Board also recommends the following:

- A. As always, pharmacy services must be safely and properly provided at all times. Pharmacies should take proactive steps to prevent the spread of germs and to protect Kansas patients. Proper cleaning, sanitizing, and disinfection procedures must be in place. See CDC's guidance for keeping the workplace safe. https://www.cdc.gov/coronavirus/2019-ncov/downloads/workplace-school-and-home-quidance.pdf
- B. The United States Environmental Protection Agency (EPA) has published an online listing of disinfectant products approved for use against SARS-COV-2, the coronavirus that causes COVID-19. The EPA list and other EPA virus related information is available online at https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2.
- C. Pharmacy staff should be trained on how to recognize symptoms of potential illness and what to do if they develop symptoms or come in close contact with a person known to have COVID-19. See the materials from KDHE and CDC as listed above.
- D. The Board recommends establishing procedures for staff to report potential symptoms or COVID-19 exposure to pharmacy management/the pharmacist-in-charge. Pharmacy management should be trained on appropriate response measures, including any quarantine requirements. The CDC recommends that workers stay home if they are feeling sick or have a sick family member in their home.
- E. Make sure pharmacy staff are trained on and use proper handwashing techniques. CDC handwashing recommendations are available online at: https://www.cdc.gov/coronavirus/2019-ncov/about/prevention.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fabout%2Fprevention-treatment.html
 A free CDC handwashing video is also available online at: https://www.youtube.com/watch?v=d914EnpU4Fo.

TEMPORARY PHARMACY CLOSURE

The Board recognizes that situations could occur that may require the pharmacy to temporarily close. Planning is key! The Board encourages licensees to take proactive steps to adopt emergency response plans before an actual emergency occurs.

In the event a pharmacy has to temporarily close, licensees should take proactive steps to assist patients and avoid interruptions in patient care:

- A. Provide patients as much advance notification as possible. The Board recommends posting signs/notifications in a publicly visible location such as on main entry doors, near the pharmacy area, and on the pharmacy's website. Other direct patient notification options should also be considered (e.g., HIPAA compliant texts/e-mails).
- B. Patients should be provided instructions and contact information for contacting the pharmacy/speaking with a pharmacist (phone number/e-mail). To avoid medication interruptions, the Board recommends providing directions for transferring prescriptions, if necessary.
- C. Notify the Board by <u>email</u> if the pharmacy must temporarily close (more than one day) due to COVID-19 and provide follow-up email notification when the pharmacy reopens.

D. Remote – Kansas does not have any regulation that would allow a pharmacist not licensed by Kansas or not working for a Kansas-registered nonresident pharmacy to provide remote services to a pharmacy in Kansas.

REUSE OF GARB FOR STERILE COMPOUNDING PHARMACIES

Licensees have expressed concerns with potential shortages of gowns, face masks, and shoe covers. The Board recommends talking with your supplier. If a shortage is anticipated, pharmacies should first consider measures to conserve supplies they have on hand. Potential measures could include limiting the number of personnel entering the buffer room/controlled area and modifying staging activities to minimize trips into the buffer room/controlled area.

The Board recommends watching the CriticalPoint® webinar "COVID-19: Downstream Implications for Sterile Compounding" available on their website: https://www.criticalpoint.info/

The Board has approved the reuse of masks per CriticalPoint® suggestion. Please make sure to update policy and procedures and to train staff if there are any changes to current practices.

Note: CriticalPoint® information is being provided for informational purposes only. The webinar was conducted by a private entity and is not officially endorsed or sponsored by the Board. Recommendations/suggestions are solely those of CriticalPoint® and do not necessarily represent the opinions/recommendations of the State of Kansas. In the event of a conflict, Kansas law will apply.

USP has provided recommendations, which can be found on their website: https://www.usp.org/sites/default/files/usp/document/about/public-policy/usp-covid19-garb-and-ppe.pdf. And the FDA has also issued a letter to healthcare providers on surgical mask and gown conservation strategies, and a letter regarding glove conservation.

Facilities should decide on and document plans for change and the basis for those changes, including research and guidance. This is a temporary allowance due to shortages resulting from COVID-19.

On April 20, 2020, the FDA released a temporary policy regarding non-standard PPE practices for sterile compounding. Visit: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/temporary-policy-regarding-non-standard-ppe-practices-sterile-compounding-pharmacy-compounders-not

Reassessment will be June 30, 2020.

EMERGENCY REFILLS

As a reminder, emergency refills are addressed in K.S.A. 65-1637(k)(2) which states:

"A pharmacist may refill a prescription order issued on or after the effective date of this act for any prescription drug, except a drug listed on schedule II of the uniform controlled substances act or a narcotic drug listed on any schedule of the uniform controlled substances act, without the prescriber's authorization when all reasonable efforts to contact the prescriber have failed and when, in the pharmacist's professional judgment, continuation of the medication is necessary for the patient's health, safety and welfare. Such prescription refill shall only be in an amount judged by the pharmacist to be sufficient to maintain the patient until the prescriber can be contacted, but in no event shall a refill under this paragraph be more than a seven-day supply or one package of the drug. However, if the prescriber states on a prescription that there shall be no emergency refilling of that prescription, then the pharmacist shall not dispense any emergency medication pursuant to that prescription. A pharmacist who refills a prescription order under this paragraph shall contact the prescriber of the prescription order on the next business day subsequent to the refill or as soon thereafter as possible. No pharmacist shall be required to refill any prescription order under this paragraph. A prescriber shall not be subject to liability for any damages resulting from the refilling of a prescription order by a pharmacist under this paragraph unless such damages are occasioned by the gross negligence or willful or wanton acts or omissions by the prescriber."

The Board will not pursue disciplinary action against licensees or registrants that dispense emergency refills to patients in accordance with the above provisions for <u>up to 30 days</u> in the pharmacist's discretion through May 31, 2020. Total dispensing per prescription should not exceed a 30-day supply. The Board recommends documenting the authorization agent as "COVID-19 emergency" in the patient record."

HAND SANITIZER

The FDA has published guidance on the temporary compounding of hand sanitizer by pharmacies and outsourcing facilities during this emergency period. This guidance can be found at https://www.fda.gov/media/136118/download. During the emergency period, the Board will allow over-the-counter compounding of hand sanitizer without a prescription only when the FDA guidance document, including the information regarding formulation and labeling, is being followed exactly. This allowance is in effect until rescinded by the Board as published and noticed on the Board website. The Board does expect all applicable compounding documentation to be maintained in accordance with Kansas compounding regulations for any hand sanitizer products made by registered facilities during this time.

The World Health Organization (WHO) has provided more specific information on compounding hand sanitizer, including the amounts of each ingredient and mixing instruction to achieve the concentrations outlined in the FDA guidance: https://www.who.int/gpsc/5may/Guide to Local Production.pdf

USP also provided information for <u>Compounding Alcohol-Based Hand Sanitizer during the</u> COVID-19 Pandemic.

The Board has become aware of local distilleries manufacturing hand sanitizer rub. The Board does not have jurisdiction over this matter but encourages pharmacies to make sure the manufacturers are following guidelines from FDA, USP, and WHO for mixing and labeling when partnering with these organizations.

BOARD RENEWALS

The Board plans to proceed with the regular renewal schedule for all licenses and registrations expiring June 30, 2020. Renewals will open on or around May 15. Once approved, facilities will be expected to print the renewed registration through the online portal – they will NOT be mailed. A renewed pharmacist license will still be mailed to the address of record. The Board's June 30, 2020 expiration date has not yet been affected by the Governor's Executive Order 20-19. Continuing education is required to be completed by June 30, 2020.

Updated information related to the new requirements and categorizations to comply with the DSCSA and K.A.R. 68-14-1 through K.A.R. 68-14-7b will be released soon.

ASHP RESOURCES

ASHP is making its resources available to pharmacists for free for the next 60 days by unlocking resources on ASHP.org including section and topical Resource Centers (e.g., <u>Emergency Preparedness</u>, Geriatrics, Inpatient Care), relevant webinars and online programs (e.g., infectious diseases, flu, diseases, and well-being and resilience), and select AJHP articles. Additionally, public access to AHFS Drug Information is available for the next 60 days with the username ahfs@ashp.org and password "covid-19."

COVID-19 Resource Center

EXPIRING CPR CERTIFICATES

Due to the unavailability of in-person training to renew CPR certificates necessary to administer immunizations, the Board is implementing a grace period for CPR certificate renewal. The pharmacist must have a current CPR card with an expiration date after March 15, 2020 and maintain a copy of the card along with this notice. Pharmacists will have until August 31, 2020 to renew the CPR certification. The Board will continue to assess whether additional extensions are necessary.

REMOTE WORK

The Board has made the decision to temporarily allow remote work by pharmacy employees. This allowance only applies to pharmacies physically located in Kansas and persons licensed or registered with the Board. This allowance is only in effect until rescinded by the Board as published and noticed on the Board website. The Board expects nonresident pharmacies to allow remote work only in accordance with guidance issued by the governing body in the resident state. The Board guidelines for remote work are as follows:

Pharmacies:

- Remote workers must have secure, electronic access to the pharmacy prescription processing software.
- Any technology used must meet HIPAA compliance standards. The Board also expects
 HIPAA safeguards to be in place at the location of remote work so that non-employee persons
 present at the location are not able to see or have access to patient information.
- The Board will not offer guidance as to whether a pharmacy's established processes meet federally-required security and privacy standards.
- The pharmacy must maintain a document (for 5 years) at the pharmacy that includes:
 - o A list of all employees working remotely which shall include:
 - Name and license/registration/permit number of the employee
 - Address where the employee will be located when performing the remote activities
 - Phone number where the employee can be reached when performing the remote activities
 - The date range that the pharmacy conducted remote work activities
- All remote activities must be able to meet Kansas requirements for recordkeeping and documentation including, but not limited to, tracking the specific personnel who performed various steps in the dispensing process.
- All physical dispensing activities (tablet counting, packaging, labeling, compounding, etc.) and final product review must occur on-site at the pharmacy.
- Nothing in this guidance is intended to allow a pharmacy to be open without a pharmacist physically present at the pharmacy. See K.S.A. 65-1637c.

Pharmacists:

- The pharmacist must be licensed in Kansas.
- Any supervision of technicians, including those working remotely, must be conducted by a
 pharmacist physically located at the pharmacy. A pharmacist working remotely may not
 supervise a technician.
- The 4:1 technician to pharmacist ratio is still in effect and includes any technician working remotely. See updated K.A.R. 68-5-16, effective February 7, 2020.

Technicians:

 Only grandfathered technicians and technicians that have passed an approved national certification exam may work remotely. This includes technicians with 14- prefixes to their registration number. Technicians with 24- prefixes to their registration number are not allowed to work remotely.

- Technicians may only work remotely during the pharmacy's regular business hours.
- Technicians may perform the following tasks when working remotely:
 - Data Entry
 - Order Entry (hospital pharmacies)
 - o Refill queue processing
 - Sending refill requests to prescribers by automated methods
 - Insurance Processing or Billing
 - Contacting patients for clarification of personal data and insurance processing information (i.e., date of birth, insurance information, etc.)
 - Please note: Patients may be unwilling to provide personal information to a person calling from a phone number unrelated to the pharmacy. Please do not be forceful with patients in these situations and have the technician contact the pharmacy to call the patient directly.
- While working remotely, technicians may not:
 - o Directly contact prescribers or prescriber offices for clarifications or refills
 - Directly contact patients for issues related to medication therapy.
 - Please note: This list is not exhaustive and the supervising pharmacist should rely on the aforementioned list of approved activities to direct technicians.
- Any technician working remotely must maintain direct communication capabilities with the supervising pharmacist (located at the pharmacy) at all times. A video component is not required.
- Electronic supervision services are separate from remote supervision allowance provides by the Board. Electronic supervision is already allowed for hospital pharmacies for the supervision of one technician per pharmacy. The pharmacist may still supervise up to the 4:1 technician ratio. See K.A.R. 68-22-1 through K.A.R. 68-22-5.

For interns:

- Interns may work remotely to perform technician functions and are expected to follow the guidelines for technicians. Any hours spent working remotely to perform technician duties shall not count towards the intern hours required by the Board.
- Interns may complete non-patient intern hours remotely through journal clubs, drug updates, presentations, etc. at the direction and discretion of the school and preceptor.

DISPENSING CERTAIN MEDICATIONS

The Board strongly encourages vigilance in processing <u>new</u> prescriptions for chloroquine and hydroxychloroquine and recommends reaching out to prescribers to verify diagnosis. Recent concerns regarding an increase in the issuance of prescriptions for these medications for prevention and treatment of COVID-19 indicate pharmacists should exercise caution dispensing these medications in a community setting.

There are currently no FDA approved therapeutics or drugs to treat, cure or prevent COVID-19; however, there are FDA-approved treatments that may help ease the symptoms. The FDA emergency use of chloroquine and hydroxychloroquine for COVID-19 patients may be obtained from the strategic national stockpile and should only be used in the hospital, inpatient treatment setting. The FDA has not indicated any approved use in outpatient or community dispensing settings. If used, medications should be restricted to patients who are admitted to hospitals with COVID-19 infections and individual patient care should be discussed with an infectious diseases provider at the healthcare facility. Medication side effects, drug

interactions, contraindications, and laboratory monitoring requirements should also be considered. For clarification from the FDA, visit https://www.fda.gov/media/136534/download and https://www.fda.gov/media/136537/download.

Pharmacists must also consider that patients currently taking hydroxychloroquine for FDA approved indications (i.e.: lupus, rheumatoid arthritis) could be affected by increased prescribing. Supplies of chloroquine and hydroxychloroquine should be monitored by pharmacists for medication availability.

The Kansas Board of Healing Arts and Kansas Board of Nursing have also published guidance on this topic.

SICK PHARMACY PERSONNEL

The Board understands that each community has different pharmaceutical needs and levels of services available. The Board expects that each pharmacist will use professional judgement in determining the safest course of action for themselves, their employees, and their patients in the event of illness. The Kansas Pharmacists Association is creating a voluntary registry for pharmacists, technicians, and interns that are willing and able to cover shifts. This registry will be available as a resource for pharmacies needing staffing coverage. To volunteer, visit: https://kansaspharmacistsassociation.wildapricot.org/COVID-19.

FINGERPRINTING AND INITIAL APPLICATIONS

Due to the closure of fingerprinting locations, the Board is working with the KBI to run a name-based background check for provisional licensure or registration with the Board. Individuals will still need to honestly answer the disciplinary questions on the application, submit a completed S-150 depending on the answers to the disciplinary questions, and the S-100 waiver form except the bottom will not need to be completed by the fingerprinting agency.

Provisional licenses and registrations will be issued with an expiration date of August 31, 2020 to allow sufficient time for applicants to be fingerprinted once locations reopen. Upon receipt of the completed fingerprints and KBI/FBI criminal background check, the Board will reevaluate the registration or license application. If the full background check is consistent with the original application, the Board will extend the expiration date of the license or registration to the regular expiration date for no additional fee. If the full background check is inconsistent with the original application, the license or registration will be revoked. The Board will deny applications that misrepresent or fail/forget to report any criminal offense history.

Completed applications will be processed after April 6, 2020 in the order they are received and will be evaluated for issuance based on the Board's statutory criteria.

DEA GUIDANCE ON PRESCRIBING AND DISPENSING CONTROLLED SUBSTANCES

In light of the Public Health Emergency, DEA recognizes that it may not be feasible for a practitioner to deliver a Schedule II controlled substance follow-up paper prescription to the pharmacy within 7 days as required by 21 CFR 1306.11(d)(4). Therefore, the DEA has granted practitioners 15 days within which to provide that prescription to the pharmacy. This exception is limited to emergency oral prescriptions only. Make sure to maintain a copy of the prescription in the patient records. The Board concurs with DEA's exception to the regulations in Kansas until it is rescinded by the DEA. For additional information from the DEA, visit https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-

021)(DEA073)%20Oral%20CII%20for%20regular%20CII%20scirpt%20(Final)%20+Esign%20a.pdf.

The DEA has also provided a decision tree for prescribing and dispensing of controlled substances during the public health emergency, which is very useful. Please review it at:

https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-023)(DEA075)Decision Tree (Final) 33120 2007.pdf?fbclid=IwAR17GqSeVEN2L5eU2ZExer 5vPuies_7YusN05U93SZAs3PJIJ1n8dsnYMZU.

The Board will not pursue disciplinary action against licensees or registrants that operate in accordance with the DEA COVID-19 5% rule exception.

https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-029)(DEA-085) DEA 5 percent practitioner exception (final).pdf

GUIDANCE FROM KANSAS HEALING ARTS AND NURSING

The <u>Kansas Board of Healing Arts</u> and the <u>Kansas Board of Nursing</u> have also been providing guidance to the public concerning waivers of their statutes and regulations. Many of these pertain to the prescribing of medications or relate to the practice of pharmacy. Please review their guidance, as well.

EXAMINATIONS AND TESTING

Pearson Vue is reopening testing sites with 50% capacity (not greater than 10 persons/site at a time due to social distancing guidelines), and will continue to open remaining sites on a daily basis. While this will continue to limit the number of individuals and the locations available for pharmacists and technicians to schedule and take examinations, the Board encourages taking steps to schedule any upcoming exams promptly. For more information, visit: https://home.pearsonvue.com/.